



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/237,291	01/25/1999	JUDY CAROL YOUNG	SYS-2068	9391

1095 7590 03/31/2008

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER

MONTANARI, DAVID A

ART UNIT	PAPER NUMBER
----------	--------------

1632

MAIL DATE	DELIVERY MODE
-----------	---------------

03/31/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/237,291	Applicant(s) YOUNG ET AL.	
	Examiner DAVID MONTANARI	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-20, 23-26, 31-43, 46, 47, 52 and 53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-20, 23-26, 31-43, 46, 47, 52 and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/25/2007 has been entered.

1. Claims 18, 23, 37 and 52 are amended.
2. Claim 53 is new.
3. Claims 18-20, 23-26, 31-43, 46, 47, 52 and 53 are examined in the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-20, 23-27, 31-34, 37-43, 46-47, and 52-53 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Dao et al. (01/15/1997, Blood, Vol. 89, pgs. 446-456) in view of Young et al. (09/01/1996, Blood, Vol. 88, pgs. 1619-1631) for reasons of record in the office actions mailed on 11/03/2005, 7/6/2006 and 2/12/2007.

Response to Arguments

Applicants argue in amendment filed on 9/25/2007 that claim 18, 23, 37 and 52 have been amended to recite that the concentration range of TPO used in the claimed method does not

Art Unit: 1632

cause differentiation of the human pluripotent hematopoietic stem cells. Applicants continue that claims 20 and 40 have been amended to omit this limitation and that new claim 53 includes this limitation. Accordingly, Applicants argue that the inventions recited in independent claims 18, 23, 27 and 52-53 are non-obvious over the disclosure of Dao and Young, and that the dependent claims are patentable for at least the same reasons. These arguments are not persuasive.

Young et al. address this issue regarding TPO and differentiation on pg. 1625 Col. 2 under the "Blast Cell" outgrowths from single PHP heading. Young et al. teaches that approximately 75% of the single CD34+Thy-1+Lin- cells from ABM that proliferated in the presence of TPO did not display differentiation to morphologically mature MK. Further Young et al. teaches a rationale for why differentiation is occurring, mainly IL-3. Young et al. states that "IL-3 plus TPO produced much more cell proliferation than TPO alone but drove cells to differentiate (detected by loss of CD34 expression)". Further Young et al. states that "The effects of IL-3 appeared to override the effects of TPO, because TPO plus IL-3 gave similar results to IL-3 alone for cell activation, cycling, and loss of CD34 expression" (pg. 1630, col. 1 lines 6-12). With regard to new claim 53, the method of promoting the expansion of a population of human pluripotent hematopoietic stem cells using the same recited steps as recited in independent claim 18 would also be obvious in view of the teachings of Dao and Young. Practicing claim 18 or the combined teachings of Dao and Young, the ordinary artisan would have a reasonable expectation of success to promote the expansion of a population of said cells using the recited steps and conditions in claim 18. Thus the ordinary artisan, in view of Applicants' amendments to the above stated claims would still be motivated to combine and use the teachings of Dao et al. and Young et al. and thus for reasons of record and above the rejection is maintained.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID MONTANARI whose telephone number is (571)272-3108. The examiner can normally be reached on M-Tr 8-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David A. Montanari, Ph.D.
AU 1632

/Anne-Marie Falk/
Anne-Marie Falk, Ph.D.
Primary Examiner, Art Unit 1632